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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,768

01/17/2006

Bernhard Kohl

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

12/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,768	Applicant(s) KOHL ET AL.	
	Examiner GREGG POLANSKY	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/03/2008 has been entered.
2. Applicants' response, filed 10/03/2008, to the Office Action mailed 7/03/2008 is acknowledged.
3. The Declaration under 37 CFR 1.132 filed 10/03/2008 is acknowledged and has been reviewed.
4. Claims 1-10, 13 and 14 are pending.
5. Claims 1-5, 7, 13, and 14 are presently under consideration.
6. Applicants' arguments and Declaration have been fully considered but are moot in view of the new ground(s) of rejection. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-5, 7, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recites the limitation "at least one positive charge equivalent of a metal ion is counterbalance by a hydroxyl ion" (emphasis added). There is insufficient antecedent basis for this limitation in the claim. It is not clear if "a metal ion" is referring to the metal of the metal salt of a pyridine-2-ylmethylsulphonyl-1H-benzimidazole or to another metal ion.

10. Claims 3 and 4 recite "Me is a pharmacologically acceptable two-valued metal ion" (see line 6 of each claim). It is unclear what a "two-valued" metal ion is.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-5, 7, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a **New Matter** rejection.

13. Instant Claim 1 recites "A pharmacologically compatible metal salt of a pyridin-2-ylmethylsulphonyl-1H-benzimidazole with H^+/K^+ -ATPase-inhibitory activity, in which at least one positive charge equivalent of a metal ion is counterbalanced by a hydroxyl ion, or a hydrate thereof." The application as originally filed does not disclose a metal ion

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not associated with a pyridin-2-ylmethylsulphinyl-1H-benzimidazole, as the presently amended Claim 1 does. This is a broadening of the metal embodiments over what was originally filed.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

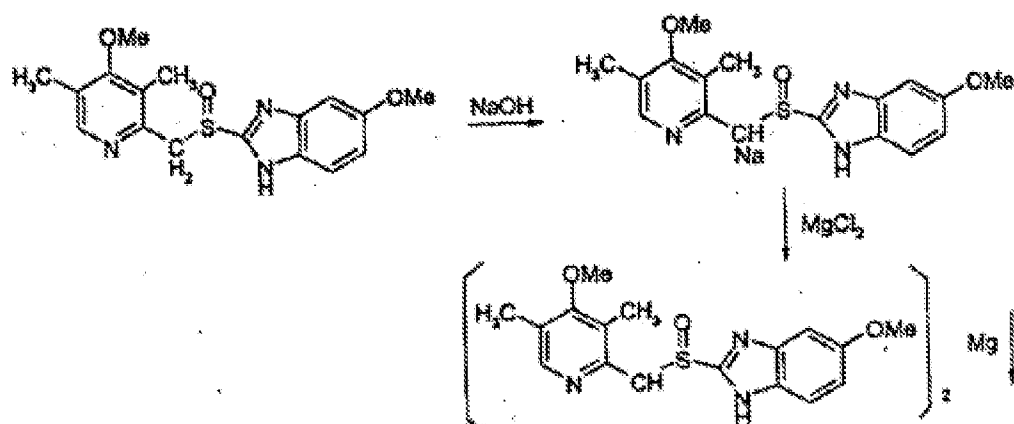
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui et al. (Chinese Patent Publication No. 1367172, including English translation).

Cui et al. teach a process of making magnesium salts of substituted pyridine-2-ylmethylsulfinyl-1H-benzimidazole derivatives, including pantoprazole, and that the derivatives can be used as proton pump inhibitors. See last line on page 3 and 2nd paragraph on page 4 of the translation. Cui et al. teach the preparation of these compounds involves dissolving the substituted pyridine-2-ylmethylsulfinyl-1H-benzimidazole compound in alkaline aqueous solution adjusted to pH 9-13, followed by the drop-wise addition of a water-soluble magnesium salt solution (e.g., MgCl₂ or Mg(NO₃)₂) and the precipitate collected. The figure on page 6 of the English translation of the Cui et al. reference is provided below:

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When NaOH is added to the reaction mixture (prior to the addition of MgCl₂), a pharmacologically compatible metal (sodium) salt of omeprazole (or another substituted pyridine-2-ylmethylsulfinyl-1H-benzimidazole derivative, such as pantoprazole) is formed. Simultaneous to the formation of the sodium omeprazole salt, sodium not associated with omeprazole is counterbalanced by a hydroxyl ion (meeting the requirements of instant Claim 1).

During a drop-wise addition of MgCl₂, a magnesium salt of omeprazole is formed. Sodium ions associated with hydroxyl ions still present in the reaction mixture continues to satisfy the requirement of instant Claim 1 of “a metal” counterbalanced by a hydroxyl ion.

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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17. Claims 1, 2, 7, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al., as applied above, in view of Kohl (U.S. Patent No. 6,410,569 B1).

The teachings of Cui et al. have been presented *supra*.

Cui et al. do not teach *per se* a composition comprising an auxiliary agent.

Kohl teaches a pharmaceutical composition comprising pantoprazole magnesium dihydrate and an auxiliary, and its use in a method of treating amenable disorders of the stomach or intestine. See column 4, claims 1, 2, and 8. Kohl teaches the increased stability of the magnesium salts of pantoprazole. See column 1, last paragraph. Indeed, Kohl presents evidence of the stability of the magnesium pantoprazole salt that is comparable to that presented in the instant Specification. See Kohl reference, column 3, 1st paragraph, and instant Specification, page 5, lines 14-18.

One of ordinary skill in the art at the time of the invention would have known that proton pump inhibitors were useful for the treatment of disorders of the gastrointestinal system, as taught by both Cui et al. and Kohl, and that effective compounds must be formulated with pharmaceutically acceptable auxiliary agents (e.g. carriers, diluents, disintegrants, etc.). The artisan would have found it obvious to combine the teachings of the two references cited above, motivated by the need to make pharmaceutical compositions of pantoprazole, having greater stability, for use in treating gastrointestinal disorders.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

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Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

18. Claims 1-5, 7, 13, and 14 are rejected.

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1611

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614